BROOKSTEIN DECLARATION EXHIBIT 4

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Grafton et al.

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(54) **HIGH STRENGTH SUTURE MATERIAL**

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(51) **Int. Cl.**[7] **A61L 17/04**
(52) **U.S. Cl.** **606/228**
(58) **Field of Search** 606/228

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,942,532 A		3/1976	Hunter et al.	
4,047,533 A	*	9/1977	Perciaccante et al.	606/230
4,344,908 A		8/1982	Smith et al.	264/203
4,411,854 A		10/1983	Maurer et al.	264/205
4,422,993 A		12/1983	Smith et al.	264/210.8
4,430,383 A		2/1984	Smith et al.	428/364
4,436,689 A		3/1984	Smith et al.	264/204
4,668,717 A		5/1987	Lemstra et al.	523/322
5,019,093 A	*	5/1991	Kaplan et al.	606/228
5,067,538 A		11/1991	Nelson et al.	152/451
5,234,764 A		8/1993	Nelson et al.	428/364
5,261,886 A	*	11/1993	Chesterfield et al.	606/228
5,318,575 A		6/1994	Chesterfield et al.	606/151
5,383,925 A	*	1/1995	Schmitt	623/1.53
5,403,659 A		4/1995	Nelson et al.	428/364
5,540,703 A		7/1996	Barker, Jr. et al.	
5,630,976 A		5/1997	Nelson et al.	264/210.8
5,720,765 A	*	2/1998	Thal	606/232
6,045,571 A	*	4/2000	Hill et al.	606/228
6,063,105 A	*	5/2000	Totakura	606/228

FOREIGN PATENT DOCUMENTS

EP 0561108 A2 9/1993

OTHER PUBLICATIONS

"SecureStrand™ Cable System," Surgical Dynamics, Inc. 1999.

* cited by examiner

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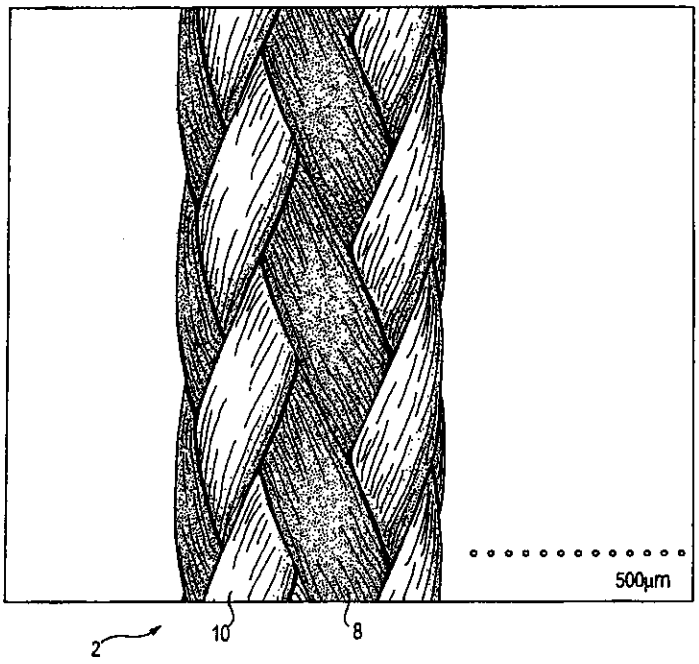
(57) **ABSTRACT**

A high strength abrasion resistant surgical suture material with improved tie down characteristics. The suture features a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester. The cover surrounds a core formed of twisted strands of ultrahigh molecular weight polyethylene. The suture, provided in a #2 size, has the strength of #5 Ethibond, is ideally suited for most orthopedic procedures, and can be attached to a suture anchor or a curved needle.

9 Claims, 2 Drawing Sheets



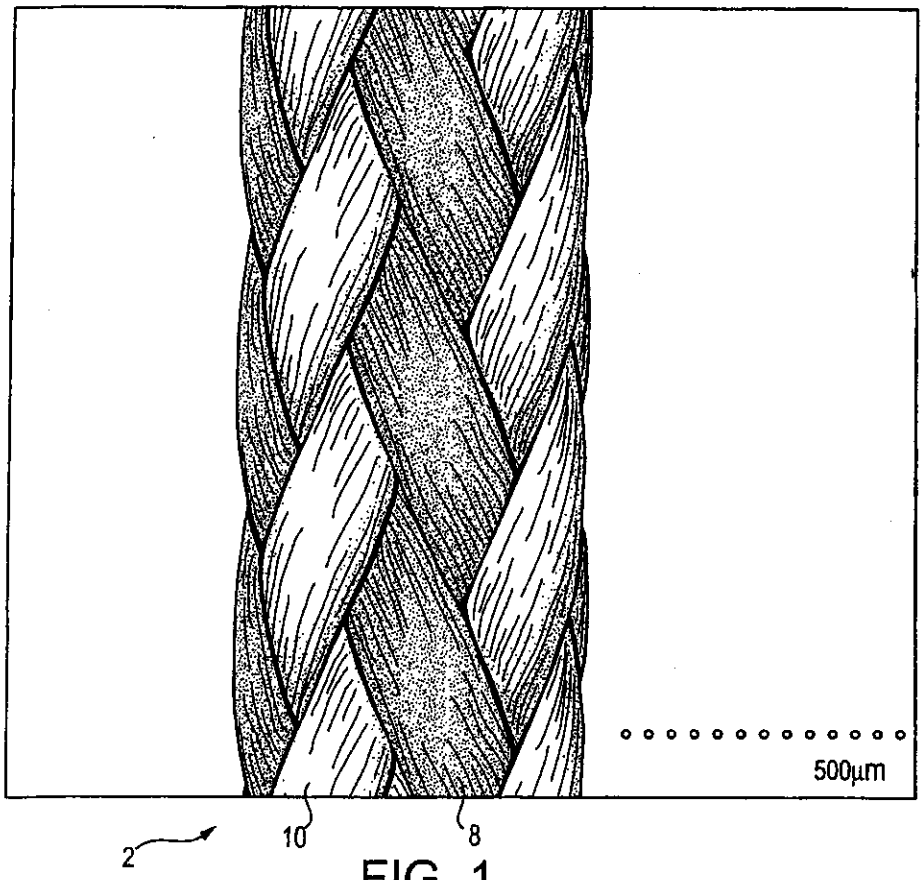


FIG. 1

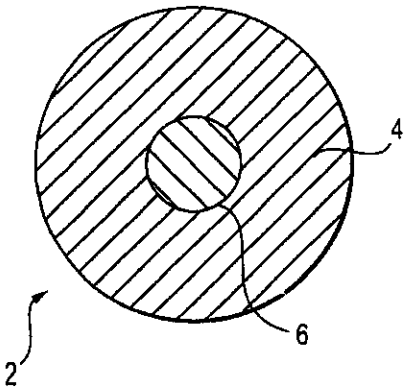


FIG. 2

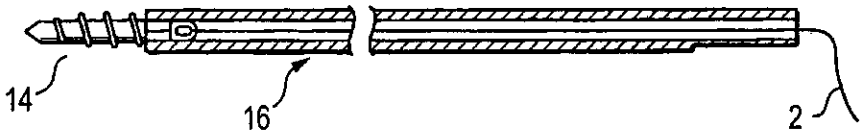


FIG. 3

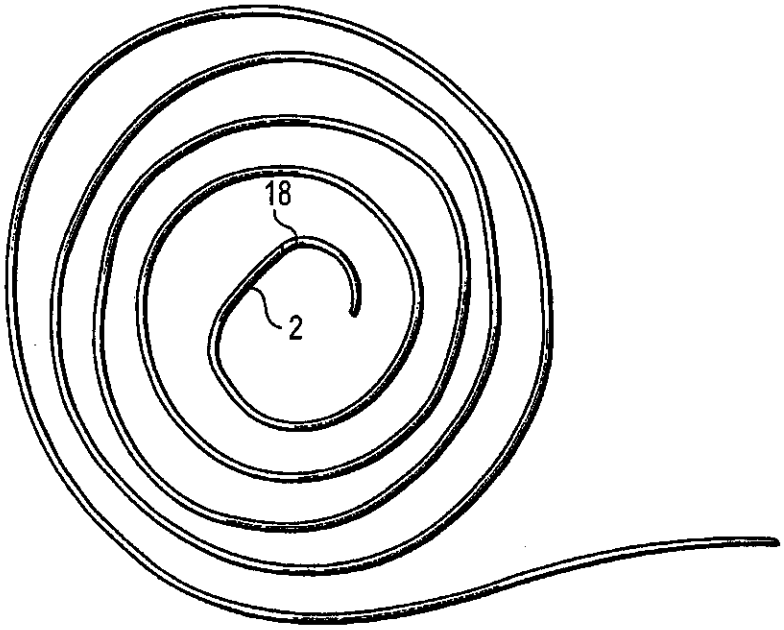


FIG. 4A

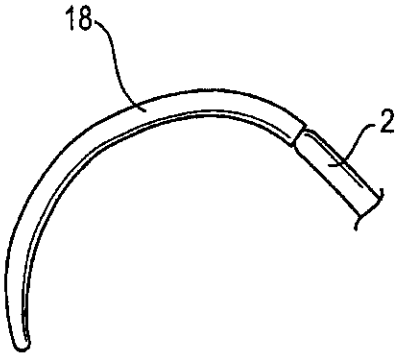


FIG. 4B

HIGH STRENGTH SUTURE MATERIAL

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to high strength surgical suture materials, and more particularly to braided suture blends of ultrahigh molecular weight polyethylene and polyester having high strength and excellent tie down characteristics.

2. Description of the Related Art

Suture strength is an important consideration in any surgical suture material. One of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain weight polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema or Spectra. However, this material, while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications.

SUMMARY OF THE INVENTION

The present invention advantageously provides a high strength surgical suture material with improved tie down characteristics. The suture features a braided cover made of a blend of ultrahigh molecular weight long chain polyethylene and polyester. The polyethylene provides strength. The polyester provides improved tie down properties.

The preferred suture includes a multifilament cover formed of a plurality of fibers of ultrahigh molecular weight polyethylene braided with fibers of polyester. The cover surrounds a core of twisted fibers of ultrahigh molecular weight polyethylene.

Preferably, the ultrahigh molecular weight polyethylene includes about 60% of the cover fibers, with polyester making up about 40% of the cover filaments. The core comprises about 30% of the suture, the cover making up about 70%. As an enhancement, the suture is provided with a coating on the cover, as is known in the prior art. The suture can be packaged ready for use attached to a suture anchor.

Ultrahigh molecular weight polyethylene fibers suitable for use in the present invention are marketed under the Dyneema trademark by Toyo Boseki Kabushiki Kaisha.

The suture of the present invention advantageously has the strength of Ethibond #5 suture, yet has the diameter, feel and tie ability of #2 suture. As a result, the suture of the present invention is ideal for most orthopedic procedures such as rotator cuff repair, archilles tendon repair, patellar tendon repair, ACL/PCL reconstruction, hip and shoulder reconstruction procedures, and replacement for suture in anchors.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING(S)

FIG. 1 is a copy of a scanning electron micrograph of a length of suture according to the present invention.

FIG. 2 is a schematic cross section of a length of suture according to the present invention.

FIG. 3 is an illustration of the suture of the present invention attached to a suture anchor.

FIGS. 4A and 4B show the suture of the present invention attached to a half round, tapered needle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1, a scanning electron micrograph of a length of suture 2 according to the present invention is shown. Suture 2 is made up of a cover 4 and a core 6 surrounded by the cover. See FIG. 2. Strands of ultrahigh molecular weight polyethylene (UHMWPE) 8, sold under the tradename Dyneema or Spectra, and strands of polyester 10 are braided together to form the cover 4. The core is formed of twisted UHMWPE.

Details of the present invention will be described further below in connection with the following examples:

EXAMPLE 1

USP Size 5 (EP size 7)

Made on a 16 carrier Hobourns machine, the yarns used in the braided cover are polyester type 712 and Dyneema SK65. The cover is formed using eight carriers with one end of 190 d'tex polyester per carrier, and eight carriers with one end of 220 d'tex Dyneema per carrier. The core is formed of Dyneema using one end of 440/1/3 twisted 10 tpi "z" and 7 tpi "s" (core is not steam set). Picks per inch (PPI)=36. In forming the suture, the percent cover is 71.31, while the percent of the core is 28.69. Runnage is 1991 meters per kilo.

Of the overall suture, the polyester in the cover (8 carriers×190 d'tex=1520 d'tex) makes up 33.04% of the suture, and the Dyneema in the cover (8 carriers×220 d'tex=1760 dtex) makes up 38.76% of the suture. The Dyneema core (3 carriers×440 d'tex=1320 d'tex) is 28.69% of the suture.

EXAMPLE 2

USP Size 2

The suture is 38.09% polyester, 61.91% UHMWPE, or about 40% polyester and about 60% UHMWPE.

The examples above are for size 2 and size 5 sutures. In the making of various sizes of the inventive suture, different decitex values and different PPI settings can be used to achieve the required size and strength needed. In addition, smaller sizes may require manufacture on 12 carrier machines, for example. The very smallest sizes are made without a core. Overall, the suture may range from 5% to 90% ultrahigh molecular weight polymer (Dyneema), with the balance formed of polyester.

The suture is preferably coated with a silicon based coating to fill in voids and provide optimum run down.

The Dyneema component of the present invention provides strength, and the polyester component is provided to improve tie ability and tie down characteristics. However, it has been found that the Dyneema provides an unexpected advantage of acting as a cushion for the polyester fibers, which are relatively hard and tend to damage each other. The Dyneema prevents breakage by reducing damage to the polyester when the suture is subjected to stress.

According to an alternative embodiment of the present invention, a partially bioabsorbable suture is provided by blending a high strength material, such as UHMWPE fibers, with a bioabsorbable material, such as PLLA or one of the other polylactides, for example. Accordingly, a suture made with about 10% Dyneema blended with absorbable fibers would provide greater strength than existing bioabsorbable suture with less stretch. Over time, 90% or more of the suture would absorb, leaving only a very small remnant of the knot.

In one method of using the suture of the present invention, the suture **2** is attached to a suture anchor **14** as shown in FIG. **3** (prepackaged sterile with an inserter **16**), or is attached to a half round, tapered needle **18** as shown in FIGS. **4**A and **4**B.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and

a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

2. The suture filament of claim **1**, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

3. The suture filament of claim **1**, wherein the polyester comprises about 40% of the braided fibers.

4. The suture filament of claim **1**, wherein the core comprises a bout 30% of the filament.

5. The suture filament of claim **1**, wherein the cover comprises about 70% of the filament.

6. The suture filament of claim **1**, further comprising a coating disposed on the cover.

7. The suture filament of claim **1**, wherein the polyester is non-absorbable.

8. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

9. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

* * * * *

BROOKSTEIN DECLARATION EXHIBIT 5

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	)	Civil Action No. 04-12457 PBS

HIGHLY CONFIDENTIAL

CONFIDENTIAL - NON-PATENT ATTORNEY'S EYES ONLY

deposition of:

BRIAN HALLETT

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
11th January 2006

MR. BONELLA: What do you mean by that?
MR. TAMBURO: -- but I take you at your word that this is the 30(b)(6) portion of the deposition, and again, to the extent that this testimony you are requesting right now is duplicative of testimony that was already given by Pearsalls in the past for this topic, topics number 4, 5, 6 and 7 of the original notice, Arthrex and Pearsalls are objecting to the duplicative testimony requested.
MR. BONELLA: Let's just move on. We will resolve it later. Exhibit 280. Do you recognize that, Mr. Hallett?
A I recognize it as it is.
Q What is Exhibit 280?
A It is a result of a batch of US2 FiberWire.
Q Exhibit 280 is batch testing results?
A Hmm hmm.
Q The tests describe in Exhibit 280 are, those tests that are run in the standard, ordinary business of Pearsalls?
A Correct.
Q Do you see the test at the intermediate stage?

A Yes.
Q Can you label in the manufacturing flowchart where that test was done? Can you label that as the intermediate stage? Okay. So, where you have labeled Exhibit 280 interim/stage on Exhibit 279 reflects the intermediate stage testing done in Exhibit 280?
A Yes.
Q If you could identify -- there is a measure stage testing in Exhibit 280; correct?
A Hmm hmm.
Q Could you label on Exhibit 279 where the measure stage testing is?
A So, do you want me to put the --
Q If you could just put, "Measure stage"? "Exhibit 280 measure stage", and there is also the stretch stage. Would you label where that is in Exhibit 279? And there is also the dye stage testing. Could you label where that is in Exhibit 279? Exhibit -- you have labeled in Exhibit 279, "Exhibit 280 dye stage", and that refers to the dye stage testing in Exhibit 280?
A Yes.
Q The dye testing that is done in Exhibit 280, is that all -- is that of samples of FiberWire

that have undergone the dyeing and scouring processes and all processes before that?
A Yes.
Q You have labeled Exhibit 280, "Stretch stage"?
A Hmm hmm.
Q On Exhibit 279; correct?
A Yes.
Q The samples -- I am sorry, the stretch stage testing that is in Exhibit 280, does that undergo the stretching in all processes before that?
A Yes.
Q The samples that have gone -- that are stretch-tested in Exhibit 280 -- I am sorry, I will rephrase the question. The samples that have been stretch-tested as reflected in Exhibit 280 have not been coated. Is that correct?
A No.
Q "No", it is not correct?
A No. It is not correct.
Q The samples that have been stretch test -- I am sorry, the samples that are tested at the stretch stage have undergone the stretching and coating processes?
A Yes.

Q Are you sure about that?
A Repeat the question again.
Q Sure. The stretch testing, samples that are tested at the stretch stage as in Exhibit 280, have they undergone the stretching and coating processes that are reflected in Exhibit 279?
MR. TAMBURO: Asked and answered, objection.
MR. BONELLA: Mr. Tamburo is going to object to questions, but unless he instructs you not to answer you have to answer the question.
A Yes.
Q The intermediate stage testing, have those samples been stretched and coated?
A Yes.
Q What is the difference between the intermediate stage testing and the stretched stage testing samples?
A They are tested before they are actually coated.
Q Which are tested before they are coated?
A The yarn. The braid.
Q The samples that are tested during the stretched stage, have they been stretched?

process?
A It is not a stretch as such, it is just -- we call it stretching because it is run through some pads just to align all of the filaments in the yarn.
Q What do you mean by that?
A Well, it just pulls it straight.
Q Pulls it straight? The material isn't stretched?
A Very minute.
Q Very minute. And then the coating that we see here, it goes through a bath or a dip of glue seal and then the FiberWire is put through?
A It is a bath. We use it as a bath.
Q "Bath". Okay. And what is the rate at which the yarn passes through the bath?
A 20 metres per minute.
Q Is that the same for all FiberWire?
A Yes.
Q And then this machine here dries it?
A There are four (inaudible) which actually dry it as it is going through.
Q And then it is wound up to a bobbin at the other end?
A To that bobbin on the other end.
Q Now, as the FiberWire yarn itself goes

through the stretching and then the coating, does the process change in anything itself?
MR. TAMBURO: Object to the form of the question, calls for a legal conclusion.
A Do I have to answer that?
MR. TAMBURO: You can answer, yes.
A It actually makes it stronger in the lubrication of the actual suture when it is being used afterwards.
MR. BONELLA: The material that is braided, the yarn, both the PET and the polyester, does any material change happen to them?
MR. TAMBURO: Object to the form of that question.
MR. BONELLA: So, no material change happens to the polyester and ultra high molecular weight polythethylene as the FiberWire goes through the stretching and coating processes?
MR. TAMBURO: Same objection.
A No.
MR. BONELLA: To the wire?
A Can you repeat the question?
Q Sure. The FiberWire yarn for all sizes of

FiberWire undergoes this stretching process here; right?
A Correct.
Q Now, when the yarn comes in and goes through the stretching process, does any material change take place during the stretching process?
MR. TAMBURO: Same objection.
A No.
MR. BONELLA: Are there any changes in the strength characteristics of the yarn after the --
A Yes.
Q Let me rephrase the question. During the stretching process, is there any change to the stretch properties?
MR. TAMBURO: Same objection.
A Yes.
MR. BONELLA: In what way?
A It gets stronger.
Q The yarn is stronger after the stretching process?
A Yes.
Q When you say, "Stronger", what type of strength are you talking about?
A The long strength of it goes up.

Q The long strength of it goes up?
A Yes.
Q How about the tensile strength?
A Yes.
Q Any other strengths that go up or down before or after the stretching process?
MR. TAMBURO: Objection, outside the scope of this 30(b)(6) notice. The questions were asked and answered already previously in the United States during the previous 30(b)(6) deposition, so I object to this line of questioning.
A The extension goes down.
MR. BONELLA: The what does?
A The extension.
Q What do you mean by extension?
A It doesn't need so much -- more stretching in the braid.
Q No more stretching in the braid. Is that something that happens after?
A Yes.
Q What does that alter in the property?
A Extension.
Q Is that the same as elongation?
A Yes.

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Q Does the modulus for the material change during the stretching process?
MR. TAMBURO: Same objection.
A I don't know.
MR. BONELLA: Is there testing done on that?
A No.
Q Do you know what I mean by, "Modulus"?
A Whether it alters.
Q Right.
A Yes.
Q Do you know what the modulus is referring to?
A I should imagine the make-up of the ultra high ...
Q The modulus I am referring to would be the slope of the stress strength, the stressed strain curve.
A The curve of the --
Q No. If you did a test, a stress strain plot for FiberWire before and after the stretching process, does the slope of that curve change at all with respect to the FiberWire?
MR. TAMBURO: Objection, calls for speculation, asked and answered.

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A I don't know.
MR. BONELLA: You don't know whether it does?
A Correct.
Q Now, in the dyeing process, what pressure is that done at? I am sorry, the coating process. The coating process. What temperature is that done at?
A I am not. 27 degrees.
Q Celsius?
A Yes.
Q Pressure? What is the pressure? Atmospheric?
A I don't know.
Q There is no pressure put into this machine?
A No.
Q Is there a solvent used in this coating?
A Yes.
Q What is that?
A Xylene (Phonetic).
Q Any other material used in the coating process?
A No.
Q What is the purpose of the Xylene?

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A It helps to penetrate the new seal coating within the braid structure. It dilutes the coating as well as attaching itself.
Q Where in the processing is the Xylene added to the machine?
A In the tank.
Q So, is the Zylene mixed together in the tank for the FiberWire to be put through it?
A That's correct.
Q Any material properties change to the FibreWire yarn itself during the stretching and the coating process?
MR. TAMBURO: Object to the form of the question. Calls for an expert conclusion, and outside of the scope of this 30(b)(6) notice.
A Change?
MR. BONELLA: Any material process altered by the ultra high molecular weight polythethylene or the polyester?
MR. TAMBURO: Object to the form of the question, calls for a legal conclusion and speculation and it has already been covered in a previous 30(b)(6) deposition.
A I don't know.
Q You don't know?

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A No.
Q Why don't you know?
A I am not sure of the question you are asking.
Q For example, the ultra high -- the FiberWire braid that goes, that comes out of the stretch, then goes through the process, after it has been coated, does anything change with respect to the FiberWire ultra high molecular weight polythethylene, or does anything change with respect to the polyester?
MR. TAMBURO: Object to the form of the question. If you want to narrow it down, it has big properties, but that is a very broad question, the way it has been worded.
A The only thing I can say is that the changes are not altered. That is the whole idea of putting the coating on, and I hope it makes it more easier for when the surgeon actually ties the knot.
Q Is there anything else that changes?
A Not that I am aware of.
Q Okay. Now, does the tensile strength change before or after the coating?
MR. TAMBURO: Objection. Same objections a previously noted.

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number 2 bobbin was before the coating, the stretching, and the bobbin after the coating stretching, is that --
A It does help.
Q It does help? Is there any other -- is there any carrier bobbins during this process?
A No.
Q There is only two bobbins, the beginning and the end?
A Yes.
Q What part of the yarn is stretched?
A There is no stretch. I have told you that. The only stretch taking place is through the pad.
Q Through the pad?
A And it is very minute. It is taking off the excess coating, and aligning all the film within that braid.
Q Is the speed at which the bobbin in moves itself the same as the output bobbin?
A Or -- it doesn't matter. I think it doesn't matter. They are bound to vary because that one is taking on more than that one over there.
Q The stretching process that you are referring to is the pads, are you saying that it

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goes to a line yarn?
A It takes off any excess coating.
Q After that?
A Yes.
Q Now, the oven process that we have here, I think you referred to it as drying and the curing?
A That's correct.
Q Is the drying process here a technical curing process, or is it just drying the yarn?
MR. TAMBURO: Object to the form of the question.
A It does.
MR. BONELLA: What do you mean by that?
A Well, it is actually acting as a -- it dries out the coating, it burns off any excess chemicals as it comes through the bath, and it acts as actually purifies the new coating.
Q Purifies it? What do you mean by that?
A Without speculation, I would just imagine it is -- fills in any gaps and makes sure it is completely covered.
Q Is there material change that takes place during the -- is there any change that takes place on the coating during the drying process?
MR. TAMBURO: Objection to the form of the

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question, and it calls for expert testimony.
A I don't know.
MR. BONELLA: You don't know? Right. Do you know the specification parameters for what tension that the yarn is under during the stretching process?
MR. TAMBURO: Object to the form of the question. That testimony -- mischaracterizing the prior testimony.
MR. BONELLA: I am sorry. Is the FiberWire under tension during the stretching process?
A Yes.
Q Where is the specification for that?
A It is written down in the process.
Q In the process. Okay. We need to go off the record.
(11.48 am)
OFF THE RECORD
(11.53 am)
MR. BONELLA: Mr. Hallett, when you referred to a pad, do you mean a rubber roller?
A Rubber pads.
Q Rubber pads. Not a roller?
A No.

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Q Can you describe the pads?
A I can show you one, if you want.
Q Can you show me one? These are the rubber pads? (Pause)
These are rubber pads. This is a white one and a brown one?
A Yes.
Q Can you describe how they work?
A The braid is sandwiched in between, so these are put in between two brackets. The brackets are screwed down as tight as possible allowing just the minimum of braid to come through. So, therefore, that does allow a little bit of stretch and it takes off the excess Nusil. So, what we have is a brown pad and a white pad and the FiberWire goes between the two.
Q The two pads remove excess coatings?
A That's correct.
Q They subtely stretch the yarn?
A Under some tension, yes.
Q Do you know what that tension is?
A Yes.
Q Is it measurable?
MR. TAMBURO: Object to the form.
A No.

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A Yes.
Q It was just the --
A That is done for the machine when it is set up for -- before they go in with a full run, to make sure the parameters are set up correctly within the machine.
Q It would be fair to say that -- wouldn't you have the input bobbin material, it goes through the stretching, coating, drying process, comes up on the take-up roller and a portion of that is sampled from over here, tested, and you can figure out what the knot pull, straight pull are, and if they are acceptable, then continue on with the process?
A That's correct.
Q Then the intermediate sample is taken at some point?
A That is done afterwards.
Q After the whole process is completed?
A Yes.
Q "Come over here, test the..."
A A percentage of that batch is tested.
Q Is tested, and that is the representative of the batch?
A Yes.
Q Then we have the measure stage testing?

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A Yes.
Q After we do the measure stage, "Come up here, do the tests again"?
A Yes.
Q Couple more questions. After the FiberWire runs through the coating, stretching process, is there a way to measure the amount of coating that is on the FiberWire?
A No.
Q Pearsalls typically doesn't do that. Okay. When the -- each FiberWire goes through two of the coating stretching processes?
A That's correct.
Q Is there a way to tell how much coating is applied in the second process versus the first process?
A No.
Q Is it less than the first process? Generally?
A I don't think so.
Q You don't think so? Well, I don't know.
MR. TAMBURO: Objection, calls for speculation.
MR. BONELLA: For the samples that are tested in the stretch and intermediate stage

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testing have they all undergone two cycles of the coating?
A They would have done, yes.
MR. BONELLA: If we could move to the final stage that would be great.
(12.40 pm)
OFF THE RECORD
(12.42 pm)
MR. BONELLA: Are we in the room where the time inspection and measuring process is performed?
A That's correct, yes.
Q What is the time inspection and measuring process performed in this room?
A It is wound to a final bobbin which is actually then sent out to the customer.
Q Any tensioning that is applied to the yarn during this process?
A Only through a clock which is actually giving the length, and the tension is given by the girls who actually control the speed of the bobbin which is taken off.
Q It is minimal tension?
A Very minimal.
Q Okay, and what is performed during this

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process?
A They are looking for any defects within the braid, and they are giving it a measured length.
Q A measured length on a spool?
A Yes.
Q What is the standard length?
A It depends on the size. On US2 I believe it is 500 metres.
Q And for US5?
A It is 250.
Q For the other sizes?
A A thousand, 500, it depends on which size.
Q For Size 0?
A That is a thousand metres.
Q 00 would probably be 2000. The 000 would be 3000. And 4000?
A 10000.
Q 0000 is 3000?
A 3000.
Q Okay, and after it undergoes this process then it goes back to the measuring in the QA in which measuring and testing is performed?
A It is labeled as well here.
Q It is labeled here? Okay. All right. Good. Thank you for your hospitality and showing us

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	Civil Action No. 04-12457 PBS

HIGHLY CONFIDENTIAL

CONFIDENTIAL - NON-PATENT ATTORNEY'S EYES ONLY

deposition of:

BRIAN HALLETT

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
12th January 2006

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affect the testing results, the knot strength testing results?
A. Not generally it doesn't.
Q. How about the testing? Can the testing show variations in the testing results?
A. Sometimes, yes.
Q. But you don't know for sure why the specifications changed?
MR. TAMBURO: Objection. Asked and answered.
A. No.
MR. BONELLA: In Exhibit 316, do you see the second column under number 5 FiberWire lists a green product?
A. Yes.
Q. Similarly, Exhibit 317, the second column lists a green number 5 FiberWire. Do you see that?
A. Yes.
Q. Has Pearsalls manufactured green number 5 FiberWire for commercial use?
A. No.
Q. The products shown on Exhibit 316, have they all been manufactured for commercial use other than the green FiberWire, number 5?
A. Yes.

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Q. How about Exhibit 317? Other than the green number 5 FiberWire, have all those other products been manufactured for commercial use?
A. Whether they have been used for commercial use, I don't really know, but these have been given those references in case -- the product has been made, and that is how they would order it.
Q. They would order it -- Arthrex orders it by the Pearsalls number?
A. PS.
Q. For example, Arthrex would order number 5 FiberWire but specifying DTPS 07?
A. That's correct.
Q. Next I will show you Exhibit 318. It is a two-page document produced to us this morning labeled, "Arthrex Products, Matrix of Label Product and Development Codes". Do you recognize Exhibit 318?
(DePuy Mitek Exhibit 318 marked for identification)
A. Yes.
Q. What is Exhibit 318?
A. What is it?
Q. Yes.
A. It is a matrix both for the development and products for the use of FiberWire and TigerWire

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Q. Have all the products listed in Exhibit 318 been sold for commercial use?
A. I don't know.
Q. How was this chart prepared?
A. It was prepared by myself and one of the engineers at Arthrex.
Q. Who? What Arthrex engineer?
A. Tara Shanoville (Phonetic).
Q. Why were -- how did you select certain products for entry into this matrix?
A. Most of them would have been what they had been regarding.
Q. What Arthrex had been ordering?
A. Yes.
Q. What about what Arthrex didn't order?
A. Similarly they were listed.
Q. Why were they listed?
A. Because it may happen at some time or not.
Q. Let's go through the chart, then. The first product, PS 30, has that been manufactured for commercial use?
A. Yes.
Q. How about the second product, PS C33? Has that been manufactured for commercial use?
A. Yes.

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Q. How about PS 12/2? Has that been manufactured for commercial use?
MR. TAMBURO: Objection. Mike, is your question, have they been sold commercially, or -- because I think he testified that they are prepared to be sold commercially, so when you say, "Are they for commercial use", it is a little confusing, because they are all really for commercial use, but the question you may want to ask is; have they been sold commercially. I am not sure.
MR. BONELLA: What I am asking, Mr. Hallett, is, typically Pearsalls sells the -- the products just aren't samples, they are providing to Arthrex. They sell the product to -- they actually sell it to RK Manufacturing or to Arthrex?
A. They would have gone -- originally they go to Arthrex.
Q. They are sold to Arthrex?
A. Yes.
Q. Not RK?
A. They go to RK, but if I made a development they normally go to Arthrex first for verification.
Q. Development, but when they are sold, the

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Q No you don't know?
A I don't know.
Q If you turn back to PR 8008, the 185/16 product with the definition of braid that we have been talking about being a braid of two different materials braided together, with that definition, does the 185/16 have a braid of two different materials braided together?
A No.
Q 185/16 is two different materials because it has one material in the core and one material in the cover?
A Yes.
Q Mr. Hallett, I will show you DePuy Mitek Exhibit 323. It is PR 7507 through 7512. Do you see the Dyneema property sheet that is attached to the document?
(DePuy Mitek Exhibit 323 marked for identification)
A Yes.
Q Have you ever seen that before? 7508 through 7512?
A Yes.
Q Yes?
A Yes.
Q Is that the market literature from Dyneema

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with respect -- I am sorry. Is 7508 through 7512 marking literature from DSM on its Dyneema product?
A That's correct.
Q Does this describe the Dyneema that was used in FiberWire?
A Yes.
Q In the back it refers to the datasheet for SK65.
A Hmm hmm.
Q Was that SK65 ever used for FiberWire?
A Yes.
Q It was?
A Sorry. I think it was SK64.
Q That was used?
A Yes, because the finer sizes, I don't think they did it in an SK65.
Q Mr. Hallett, I am going to show you DePuy Mitek Exhibit 324. It is PR 6556. Is Exhibit 324 a letter that you received from Mr. Grafton on about November 16th, 1998?
(DePuy Mitek Exhibit 324 marked for identification)
A Yes.
Q It says in the letter to you that, "We...", referring to Arthrex, "... had tested the samples of the Dyneema material". Were those

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samples 100% -- you see later down in the letter it says:
"Can you build a 25% Dyneema/75% polyester blend in a size 2 that is very flexible (like the existing suture or the ethicon sample) and send it to me to test".
Do you see that?
A Yes.
Q In the top paragraph does the sample of the Dyneema material, does that refer to a braid of 100% Dyneema?
A I can't remember.
Q Do you recall ever making a construction that was 100% ultra high molecular weight polyethylene for Arthrex?
A I can't remember.
Q In November '98 is that when FiberWire was first being developed?
A Yes.
Q What did you understand Mr. Grafton to mean when he said:
"Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible".
What did you understand that to mean?
A Yes, that he wanted a braid which was

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more -- not so stiff.
Q As the 100% ultra high molecular weight polyethylene?
A Yes.
Q He wanted Pearsalls to try to put polyester with --
A With the mixture.
Q With a braid. He wanted -- let me finish the question before you answer.
Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?
A Yes.
Q Next I will show you Exhibit 325. It is Bates number PR 6493. Do you recognize Exhibit 325 as a letter from you to Mr. Grafton from November 1998?
(DePuy Mitek Exhibit 325 marked for identification)
A Yes.
Q And the letter said:
"Please find enclosed a matrix of information of the samples that you took with you on your visit to Pearsalls, I will endeavour to proceed with the existing trial to match US2 Excel Braid

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made by Ethicon, in Polyester construction. The next Poly/Dyneema samples should be with you by the end of the week".

Do you see that?

A Yes.

Q Then you list four samples and the yarn type, and the first one is Dyneema and the next three are poly/Dyneema?

A Yes.

Q Was the first sample 100% Dyneema?

A Yes.

Q The second through fourth samples were a blend of, or a braid of polyester and Dyneema?

A Correct.

Q The 100% Dyneema had higher -- did they all have the same size? Do you know if these were all the same size, number 2, or --

A I can't remember.

Q When Pearsalls was developing the FiberWire, was it trying to -- was it comparing it against the Ethicon XL product?

A I believe it was -- I don't know whether -- what it was comparing this to, but I was asked to make a braid compared with US5, a US5 diameter.

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Q Yes, but do you see the reference to trying to match the US 2 XL braid made by Ethicon? Do you see that?

A Yes.

Q My question is; just generally in the development of FiberWire was Pearsalls comparing the products it was developing for FiberWire to Ethicon's XL products?

A Yes.

Q Was Pearsalls comparing the FiberWire products that it was developing to any other products during its development?

A Not that I can remember.

Q Next I will show you DePuy Mitek Exhibit 326. It is ARM2141 through 2147. First of all, I will see if you have any objections to the Arthrex Bates numbered document?

(DePuy Mitek Exhibit 326 marked for identification)

MR. TAMBURO: No objection.

MR. BONELLA: Mr. Hallett, is Mr. McLeod someone who works with you?

A He did work for us.

Q He has left Pearsalls?

A Yes.

Q When did he leave Pearsalls?

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A Later part of last year. He still works at -- in Pearsalls.

Q What do you mean by that?

A He has been re-employed by a company called, "Novasive".

Q Is that a company that is related to Pearsalls?

A No.

Q So, Mr. McLeod is not employed by Pearsalls?

A No.

Q No he's not employed?

A He's not employed by Pearsalls.

Q But he was?

A He was.

Q Do you see in his letter he says the first lot of PA 26 was produced as a development sample, DTPA 26?

A Hmm hmm.

Q Then he goes on to say, in the second paragraph, or the third paragraph, that:

"Future orders will be supplied against the specification PA26B".

Do you see what?

A Yes.

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Q In April 2001, is that when the -- it was decided to use the PA 6B code for number 2 FiberWire?

A It was decided, sorry?

Q It was decided to use the PA 6B code for number 2 FiberWire?

A Yes.

Q If you turn to page ARM2146, do you have that page? ARM2146? Do you see it says:

"The specification of the polyester is Type 712 and it is manufactured by KoSa GmbH & Company KG".

A Yes.

Q Is the polyester that Pearsalls has used for FiberWire always been manufactured by KoSa GmbH & Company KG?

A Yes.

Q Mr. Hallett, I will show you DePuy Mitek Exhibit 327, case number ARM2351, if you have no objections, Sal?

(DePuy Mitek Exhibit 327 marked for identification)

MR. TAMBURO: No objections.

MR. BONELLA: It says:

"The first shipment of 61,000 metres of new Blue FiberWire 2 is leaving today to RK".

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MR. TAMBURO: Object to the form, and seeking expert testimony.
A I don't know.
MR. BONELLA: You don't know?
A No.
Q What type of variation would you see to make you think it was a big increase or a big decrease between the dye stage and the measure stage?
MR. TAMBURO: Object to form.
A It could be up to about a kilo.
MR. BONELLA: How much?
A One kilo.
Q One kilo?
A Yes.
Q It could be more than that?
A Hmm hmm.
Q Could it be up to two to three kilos?
A I wouldn't think so, no.
Q You wouldn't think so. I will show you Exhibit 339. It is Bates numbers PR 3730 through 3734 and it is entitled, "Pearsalls Sutures Results for Batch 26866". Mr. Hallett, do you recognize Exhibit 339 as a Pearsalls sutures Batch Record for batch 26866?

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(DePuy Mitek Exhibit 339 marked for identification)
A Yes.
MR. TAMBURO: You don't have another copy of that?
MR. BONELLA: No. I couldn't truck over three copies of all of these. If you look at the Pearsalls sutures Works Order for Exhibit 399 it refers to the product code of 37G500500.
A Yes.
Q That is the product code for number 2 blue FiberWire?
A Yes.
Q Exhibit 339 is a record for batch 26866 for number 2 blue FiberWire?
A Yes.
Q If you look at the dye stage testing, the average knot strength, knot pull was 15.64?
A Hmm hmm.
Q Then if you look at the intermediate stage testing, it was 163990?
A Yes.
Q Then if you look at the measure stage testing, it was 15.03?
A Yes.
Q Do you know what account -- do you see

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there between the dye stage and the intermediate stage it went up by over 1 kilo?
A Yes.
Q And then at the measure stage it went down over 1 kilo from the intermediate stage?
A Yes.
Q But the difference between the dye stage and the measure stage was 0.11 kilos?
A Yes.
Q Do you know what might account for the difference between the intermediate stage and the measure stage?
MR. TAMBURO: Object to the form.
A No.
MR. BONELLA: Do you know why the dye stage and the measure stage were about the same but the intermediate stage was about a kilo greater, over a kilo greater?
MR. TAMBURO: Object to form.
A No.
MR. BONELLA: Is that a concern, that level of variation?
MR. TAMBURO: Object to form.
A No.
MR. BONELLA: Why?

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A Because I think you will see it reaches the requirements of that specific size.
Q You don't know what would cause it to go down between the intermediate stage testing and the measure stage testing?
MR. TAMBURO: Objection. Asked and answered.
A It could be the operator.
MR. BONELLA: Just the operator?
A Yes.
Q It could be how they tie the knot?
A Yes.
Q I will show you Exhibit 340. It is PR 4308 through PR 4321. It is Pearsalls sutures results for batch 25330. Do you recognize Exhibit 340 as the Batch Record for batch 5330?
(DePuy Mitek Exhibit 340 marked for identification)
A Yes.
MR. TAMBURO: Have you got another copy of that?
MR. BONELLA: No. If you go to the back you will see the product code is 25330?
A Correct.
Q Exhibit 340 is the batch record for number 2 FiberWire blue, batch 25330?

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A Yes.
Q If you look at this document you will see that the dye average -- the average knot strength at the dye stage was 16.26; right?
A That's correct.
Q And then at the intermediate stage, the average knot pull strength was 16.53, right?
A Correct.
Q And then at the measure stage, the average knot strength was 16.75?
A That's correct.
Q So, between the dye stage and the intermediate stage, the difference in the knot pull, average knot pull was less than 0.3 kilos?
MR. TAMBURO: Object to form.
A Correct.
MR. BONELLA: And the difference between the average knot strength between the intermediate stage and the measure stage was less than 0.3 kilos as well; right?
A That's correct.
Q Are these numbers, this 16.26, 16.53, 16.75, are they considered to be all about the same, based on the tolerances?
A That's right.

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Q Next I will show you Exhibit 341. It is PR 3778 through 3791 entitled, "Pearsalls Sutures Results for Batch 5899", do you recognize Exhibit 341 as the Batch Record results for batch 5899?
(DePuy Mitek Exhibit 341 marked for identification.)
A Yes.
Q Would you turn to the Work Order on PR 3791? Do you see the product code is 35G500?
A Correct.
Q Batch 25891 is for number 2 blue FiberWire?
A Yes.
Q If you look at the testing you will see that the average knot pull strength at the dye stage was 15.61, correct?
A That's correct.
Q The average knot pull strength at intermediate testing was 14.83?
A That's correct.
Q The average knot strength at the measure stage was 16.87?
A That's correct.
Q Do you know what would account for the decrease in average knot pull strength between the dye stage and the intermediate stage?

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MR. TAMBURO: Object to form and seeking expert testimony. Do you have a copy for counsel, Mr. Bonella?
MR. BONELLA: I have one copy of the Batch Records. I didn't even bring one for me.
A That is the operator testing.
Q Operator testing?
A Hmm hmm.
Q Do you know what would account for the increase in average knot pull strength between the intermediate stage and the measure stage?
MR. TAMBURO: Same objection.
A Yes.
Q What is that?
A Because it has been coated.
Q Coated?
A Hmm hmm.
Q If it increases when it is coated, we saw other ones where it decreased when it was coated?
A Very slightly.
Q In Exhibit 339, the average knot pull decreased between intermediate and measure from 16.9 to 15.53, right? That was a decrease of 1.4, right?
A Yes.
Q Do you know why that would be?

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A No. Operator.
Q What accounts for the -- so, with Exhibit 341 you are saying the decrease between the dye and the intermediate stage was due to coating?
MR. TAMBURO: Objection. Asked and answered.
A The increase.
MR. BONELLA: I am sorry, the increase, but didn't it go from -- it was 15 -- in Exhibit 341, the average knot pull in dye was 15.361, right?
A Yes.
Q That is before coating?
A Hmm hmm.
Q And the average knot pull at the intermediate stage was 14.483, right, and that is after coating?
A Hmm hmm.
Q What caused the knot pull to go down from the dye stage to the intermediate stage?
MR. TAMBURO: Objection, calls for expert testimony, asked and answered. Calls for speculation.
A I don't know.
MR. BONELLA: You don't know?

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A No.
Q How do you know at the measure stage it was -- in Exhibit 341 it was 16.482; right?
A So it is increased.
Q Check numbers. But how do you know -- it is increased. There is nothing done with the suture between the intermediate stage and the measure stage that would change the property of the suture; right?
A Hmm hmm.
Q Right?
A Yes.
Q Yes, I am correct?
A Yes, you are correct.
Q How do you know which one's right, the decreased one at the intermediate stage or the increased one at the end stage?
MR. TAMBURO: Calls for expert testimony and object to the form.
MR. BONELLA: Or were they all about the same?
A They all vary.
Q Well, if you look at the testing you cannot really say -- are they all within the tolerance of the testing so that you cannot really say that one of these values is greater than the

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other?
MR. TAMBURO: Objection, calls for exper testimony and speculation.
A Yes.
MR. BONELLA: That's correct?
A Yes.
MR. TAMBURO: Mike, this is the once-passed coating sample of US2 FiberWire. We don't have a Bates number but I will send you a Bates number by e-mail. It is a little capsule labeled, "Sample Pearsalls Limited blue FiberWire single coating 15 metres US2 batch number 28790".
MR. BONELLA: Okay. We will mark it as DP342 and ask Mr. Hallett if you can identify DePuy Mitek Exhibit 342, or take counsel's representation that it is number 2 blue FiberWire that has been run through the coating, stretching and drying process only one time. Is that correct?
(DePuy Mitek Exhibit 342 marked for identificatior
MR. TAMBURO: That is my understanding yes.
MR. BONELLA: Can he testify to that? Does he know?

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MR. TAMBURO: I think he knows only what I know. He wasn't there watching it when it was done.
MR. BONELLA: All right. I will take your representation that it is what it is.
I will show you DePuy Mitek Exhibit 343. It is a three-page document test recorded summary and sign-off sheet from Arthrex. Sal, do you have any problems in me showing him Exhibit 343? It was disclosed to J&J as non-contentious.
MR. TAMBURO: No objection.
MR. BONELLA: Mr. Hallett, I am showing you Exhibit 343. I believe it has Brian Hallett's writing on the first page, I believe it is a document from Arthrex. Have you ever seen this document before?
(DePuy Mitek Exhibit 343 marked for identification)
A Yes.
Q You have?
A Hmm hmm.
Q When did you see it?
A Sometime last year.
Q And why did you see it?
A I think it was describing or showing the

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test procedure for doing a braid load on the loops.
Q On what?
A On the loop.
Q If you look at the top it says the description of the procedure on the first page is number 2 FiberWire 2174 coated and uncoated USIPG dyed, and the date is February 16, '04, and the type of test it says, knot tiedown, and it says:
"The test objective: To determine the peak force required to advance a single half hitch using coated and uncoated Fiberwire suture".
Do you see that?
A Hmm hmm.
Q The test method is described as:
"The 50lb load cell was attached to the MTS Sintech 1/S and calibrated. A custom fixture as shown was used to simulate knot tying that would occur clinically. The top end of the suture was clamped in a custom fixture that was attached to the load cell, and then a single half hitch was tied around a guide block such that the loop length was consistent between samples. A weight of .375 kg was then attached to the free end of the suture in order to tension the loop. Care was taken to tension the legs of the suture

BROOKSTEIN DECLARATION EXHIBIT 6

Arthrex.

November 16, 1998

Brian Hallert
Pearsalls Sutures
Tancred Street, Taunton
Somerset TA1 1RY, England

FAX 011441823336824

Dear Brian:

We have tested the samples of the Dyneema material I got from you when I was at Pearsalls. They have very good tensile strength but as you mentioned they are larger in diameter than the size 2 suture we presently use. We do need for our test record more info on the 4 samples. If you could give me some basic specifications for our records I would appreciate it.

Can you build a 25% Dyneema / 75% polyester blend in a size 2 that is very flexible (like the existing suture or the ethicon sample) and send it to me to test? If we can get this blend correct, we will have a terrific advancement in suture for our soft tissue anchors.

Thank you

Don Grafton
V. P. Engineering
Arthrex Inc.

DEPUY MITEK
EXHIBIT 324
04cv12457

• Fax (941)643-6218 • Website: www.arthrex.com

BROOKSTEIN DECLARATION EXHIBIT 7

TO :Arthrex

ATTN: Don Grafton

FROM : Brian Hallett

DATE : 16/11/98

SUBJECT : POLYESTER - DYNEEMA -(Braids)

Dear Don,

Please find enclosed a matrix of information of the samples that you took with you on your visit to Pearsalls , I will endeavour to proceed with the existing trial to match the US2 Excel Braid maid by Ethicon, in Polyester construction.
The next Poly/Dyneema sample should be with you by the end of the week

Yarn	Dt-no	Runnage Mt/ Kg	St/pull KG	Diameter MM	Extention %	PPI
Dyneema	DAOI	3034	23.12	0.714	24.39	46
Poly/Dyneema	PA13	2984	36.27	0.702	18.33	48
Poly/Dyneema	PA14	3331	34.95	0.639	18.83	48
Poly/Dyneema	PA14 Stretch	3469	36.41	0.628	14.32	48

Kind regards

Brian Hallett
Product Development Manager

BROOKSTEIN DECLARATION EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

DEPOSITION OF: PETER DREYFUSS

DATE: September 16, 2005

TIME: 8:59 a.m. to 1:54 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Les Smoak, CLVS

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do on sutures.
Q. But Arthrex doesn't specifically test for how much coating has been applied on FiberWire sutures from Pearsalls?
A. No, not that I'm aware of.
Q. Has Arthrex ever rejected a batch of bulk sutures based on the amount of coating that's been applied to any FiberWire sutures?
A. Not that I know of.
Q. Okay. And then -- Okay. Now back to ARM 8784 in Exhibit 102, we've stretched and coated the suture or the braid, and what's the next step?
A. It looks -- final inspection and measuring, which would be QC.
Q. And how is that final inspection QC performed?
A. There's, as I understand, there's various steps. Mechanical measuring, and there's a -- whatever -- by feel, measuring for any imperfections.
Q. Popping maybe? Are you familiar with that term?
A. Not exactly.
Q. Okay.
A. Just making sure the suture is homogenous, consistent, and strong.
Q. Now you said mechanical measuring. What kind of mechanical measuring is used in the inspection process for

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Arthrex's FiberWire sutures?
A. There's a -- they actually measure the diameter per a certain procedure or a certain approved protocol that you measure the diameter at several places, several locations along a certain piece of suture to get an average diameter.
Q. Does Arthrex provide specifications to Pearsalls for the inspection process of its FiberWire sutures?
A. Yes.
Q. And what specifications are those?
A. Drawing -- on the drawing specifications, I would assume.
Q. Okay.
A. And possibly in an inspection procedure that we have written up in a document form.
Q. Okay. And once the braid or the bulk suture has been inspected and measured, what happens next?
A. If approved, I would assume it would be either -- well, if it's part of an order, I would assume it's then be shipped to the customer, which would be ...
Q. And then that customer -- Strike that.
The braiding process that we've talked about with respect -- Strike that.
The manufacturing process that we've talked about with respect to ARM 8784 in Exhibit 102, that testimony as

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it related to the 16-carrier bobbin applies to Arthrex's FiberWire No. 2 as sold in AR-7201; right?
A. Correct.
MR. FALKE: Why don't we break for lunch.
MR. TAMBURO: Sounds good.
VIDEOGRAPHER: Going off the record. We're off
(A lunch break was held from 11:47 a.m. to 12:47 p.m.)
VIDEOGRAPHER: Back on the record.
BY MR. FALKE:
Q. Okay, Mr. Dreyfuss, do you want to look at Exhibit 120 for a minute. The coating that's shown in Exhibit 120 and the bath of the coating, is that bath comprised of 100 percent MED-2174?
MR. TAMBURO: Object to the form.
A. I believe it is, yes.
Q. Okay. So there's no solvent or any other material used possibly to dissolve the coating?
A. I'm not aware of it, no.
Q. Okay. But you understand the coating -- the bath of MED-2174 as used in the coating process for Arthrex's FiberWire sutures to be 100 percent MED-2174?
A. I believe so.
Q. Also, if we could go back -- That's okay. I'd like you to take that sheet of paper there in front of

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you, and if you could, could you draw a cross-section of Arthrex's No. 2 FiberWire?
A. I can -- I can try, yes.
Q. And list, please -- you know -- the various materials and what not. And I'm going to mark your drawing of a cross-section of Arthrex's No. 2 FiberWire with Exhibit No. 121.
(DePuy Mitek Exhibit No. 121, drawing of Peter Dreyfuss of the Approximate Cross-Section of Arthrex 2-0 FiberWire, was marked for identification.)
A. I luckily got eight. Oh. I approximated the numbers.
Q. Okay. Did you say you drew eight?
A. I drew an eight -- a version of an eight-carrier braid.
Q. Okay. And that would be a cross-section then of Arthrex's 2-0 FiberWire suture?
A. Yes.
Q. Okay. So we're going to remark Exhibit 121 as a drawing of Arthrex's 2-0 FiberWire suture; is that correct?
A. Yes.
Q. Okay. And if you could just label that and initial and date it, please.
A. (Witness complying).

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Q. And I don't know if you did, but could you please label the core and the cover?
A. Yes, I did.
Q. Okay.
A. I was doing a core with three parts to represent the No. 2 suture. But since it's an 0, I'm not exactly sure how many yarns are made up of the core, but they're all UHMWP --
Q. Okay.
A. -- if that's acceptable.
Q. Okay. Yeah. Let me just take a look at it, please.
Okay. So but other than the core, which you're not quite sure of how many yarns make up the core on the 2-0, this outside accurately represents the cover or the sheath of the Arthrex 2-0 FiberWire?
A. Yes.
Q. Okay. And as you have shown, going around the cover or the sheath, the materials alternate PET, ultra high molecular weight polyethylene, PET, ultra high molecular weight polyethylene, et cetera?
A. Yes.
Q. Okay. Now within the sheath or the cover -- Well, first could you just label the sheath and the cover for me?

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A. (Witness complying).
Q. Are the individual yarns in the cover or sheath of the Arthrex 2-0 FiberWire as shown in 121 in contact with each other, meaning is the ultra high molecular weight polyethylene yarn connected to the neighboring PET yarn?
MR. TAMBURO: Object to the form.
A. They're all interdigitated. I'm sure there's contact between them.
Q. Intertwined?
A. Yes.
Q. Okay. So there is contact then between the neighboring or adjacent PET and ultra high molecular weight --
A. Yes.
Q. -- polyethylene yarns and the sheath or cover?
A. Yes.
Q. Okay. Next, if you could, could you please draw a cross-section of Arthrex's No. 2 FiberWire?
And -- I'm sorry. But before we go on, does Exhibit 121 reflect the construction or the structure of the 2-0 FiberWire as it's always been?
A. To the best of my knowledge, yes.
Q. Okay. So the construction with the structure as shown in 121 of a 2-0 FiberWire suture hasn't changed over

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time? Ever since Arthrex is manufacturing a 2-0 FiberWire, it's been using this configuration as shown in 121?
A. Yes.
Q. Okay.
A. (Witness complying).
Q. And I'm going to mark your drawing of Arthrex's No. 2 FiberWire suture as DePuy Mitek Exhibit 122.
(DePuy Mitek Exhibit No. 122, drawing of Peter Dreyfuss of the Approximate Cross-Section of No. 2 FiberWire, was marked for identification.)
Q. Can I take a look at it, please?
A. Yes.
Q. Okay. And so this shows a core made up of three ultra high molecular weight polyethylene yarns twisted together and then a cover or sheath composed of alternating yarns of ultra high molecular weight polyethylene and PET; is that right?
A. Correct.
Q. And the PET and ultra high molecular weight polyethylene that make up the sheath or cover of Arthrex FiberWire No. 2 are in direct contact with each other; is that right?
A. Yes.
Q. Okay. And they're intertwined around each other;

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right?
A. They're braided.
Q. Okay. Is that intertwining or --
A. Yes, they're ...
Q. Okay. And does Exhibit 122 accurately reflect the construction of Arthrex's FiberWire No. 2 currently and since its release or since it was first sold by Arthrex?
MR. TAMBURO: Object to the form.
A. I believe so.
Q. Okay. Could you mark or title Exhibit 122?
A. (Witness complying).
Q. And next I was going to ask you to draw a cross-section of the No. 5 Arthrex FiberWire suture, which I believe is the same as Exhibit 122 that you have just drawn with the exception of possibly the number of yarns that comprise the core; is that right?
A. I believe that would be correct.
Q. Okay. And -- but the outside of the cover or sheath of the Arthrex FiberWire No. 2 is the same as the cover or sheath of the Arthrex FiberWire No. 2; right?
A. In the manner of braiding, yes.
Q. Right.
MR. TAMBURO: Object to the form.
Q. In the manner as you have shown in Exhibit

No. 122?
A. Yes.
Q. I misspoke there, but the outside or the cover of the Arthrex FiberWire No. 5 is the same as the cover or sheath of the Arthrex FiberWire No. 2; is that correct?
A. That's correct.
Q. Okay. The same in terms of configuration and contact and intertwining; right?
A. Yes.
Q. Okay. Next, if I can ask you to draw the cross-section of Arthrex's No. 0 FiberWire.
A. Let's see.
Q. And I believe you testified earlier, and correct me if I'm wrong --
A. Twelve.
Q. -- that there's twelve carriers?
A. Correct.
Q. Okay. And I also believe you testified earlier that you weren't sure about how many yarns make up the core in Arthrex's Size 0 FiberWire; is that right?
A. That's correct.
Q. Okay.
A. I'm sorry; would you give me the number again?
MR. TAMBURO: Here.
A. All right.

Q. Now I'm going to mark your drawing of a cross-section of Arthrex's No. 0 FiberWire with DePuy Mitek Exhibit 123.
(DePuy Mitek Exhibit No. 123, drawing of Peter Dreyfuss of the Approximate Cross-Section of Size 0 FiberWire, was marked for identification.)
Q. And I believe what you've drawn in Exhibit 123 is that the cover or sheath of the Arthrex No. 0 FiberWire has alternating yarns of PET and ultra high molecular weight polyethylene; is that right?
A. Correct.
Q. And that -- and that those neighboring yarns in the sheath or cover are in contact with each other?
A. Correct.
Q. And in the same configuration and intertwining manner as Exhibits 122 and 121?
A. Correct.
Q. Okay. Could you draw for me a cross-section of Arthrex's FiberWire 3-0 suture? I believe you testified earlier that it's eight carriers.
A. Thank you.
Q. And I'm going to label your cross-section drawing of Arthrex's FiberWire No. 3 suture with DePuy Mitek Exhibit 124.
(DePuy Mitek Exhibit No. 124, drawing of Peter

Dreyfuss of the Approximate Cross-Section of Size 3-0 FiberWire, was marked for identification.)
Q. And just so the record's clear, all these hand drawings that you have done so far, when it says UHMW, that means ultra high molecular weight polyethylene?
A. Correct.
Q. Okay. And what you've shown is that Arthrex's No. 3-0 FiberWire has alternating yarns of PET and ultra high molecular weight polyethylene?
A. Correct.
Q. And that those neighboring yarns and the sheath or cover contact each other?
A. Correct.
Q. And they're in the same -- you know -- intertwining manner as Exhibits 123, 122, and 121?
A. Correct.
Q. And now if you could just draw for me a cross-sectional drawing of Arthrex's 4-0 FiberWire suture, please. And I'm going to mark your drawing of Arthrex's 4-0 FiberWire suture with DePuy Mitek Exhibit 125.
A. (Witness complying).
(DePuy Mitek Exhibit No. 125, drawing of Peter Dreyfuss of the Approximate Cross-Section of Size 4-0 FiberWire, was marked for identification.)
Q. And I believe what you've shown in Exhibit 125 is

that, one, there's no core in the 4-0 FiberWire; right?
A. Correct.
Q. And that the sheath or cover is made up of intertwining yarns of ultra high molecular weight polyethylene and PET?
A. Correct.
Q. And that the neighboring yarns within the cover or sheath are in contact with each other?
A. Correct.
Q. Okay. Do Exhibits 123, 124, and 125 show not only the present-day but the configuration of the FiberWire sutures as sold in the past?
A. Yes, to the best of my knowledge and --
Q. In other words, there hasn't been any different configurations of Arthrex's 0, 3-0, and 4-0 FiberWire sutures?
A. I'm not for certain on the 4-0.
Q. Okay. But for the 2-0 and the -- or for the 0 and the 3-0 you are?
A. Yes.
Q. Okay. And I don't think I asked you this, but in Exhibit 125, the alternating sheaths -- alternating yarns and the sheath or cover are in intertwining contact like Exhibits 124, 123, 122, and 121?
A. Yes.

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Q. Okay. Now what I'd like you to draw is a cross-section of Arthrex's TigerWire suture.
A. Okay. Which size? Actually, there's --
Q. That's a good question. How many sizes of TigerWire are there?
A. No, technically, there's only one.
Q. Okay. Is that a No. 2 size?
A. Correct.
Q. Okay. So just to rephrase, can you please draw a No. 2 TigerWire as sold by Arthrex?
A. (Witness complying).
Q. And I'm going to mark your drawing of No. 2 TigerWire as sold by Arthrex with DePuy Mitek Exhibit 126.
(DePuy Mitek Exhibit No. 126, drawing of Peter Dreyfuss of the Approximate Cross-Section of Size 2 TigerWire, was marked for identification.)
Q. Do you know how many carriers are in the Arthrex No. 2 TigerWire?
A. Sixteen.
Q. Sixteen. So the configuration of the sheath or cover in Arthrex's No. 2 TigerWire is exactly the same as the sheath or cover as Arthrex's No. 2 FiberWire with the exception that one of the PET carriers has been replaced with a black nylon carrier?
A. Correct.

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Q. Okay. So the sheath has alternating yarns made up of ultra high molecular weight and polyester or PET with the exception of one carrier that is black nylon?
A. Correct.
Q. Okay. And the adjacent yarns in the sheath are in contact with each other in the same intertwining manner as Exhibits 125, 124, 123, 122, and 121?
A. Correct.
Q. Okay. All right. Thank you.
Okay. Now I'd like to talk about FiberTape. Could you explain to me the process that Pearsalls goes through to manufacture FiberTape from the stage of individual yarns?
Actually -- Do you know what? I might have a document here that would help you out.
I'm going to show you what's being marked as DePuy Mitek Exhibit 127. It's a document with Bates numbers ARM 8847 through 9091.
One is double-sided; one isn't. That one goes to Sal. No. I'm sorry. That one goes to Sal.
Okay. We're talking about Exhibit No. 127.
(DePuy Mitek Exhibit No. 127, Technical File Arthrex FiberWire Volume 2, was marked for identification.)
Q. Have you seen Exhibit 127 before?

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A. Not to my knowledge, no. Not ...
Q. If you could turn to Page ARM 9003. Now you can -- I'm sorry; it's the page before also, ARM 9002.
I'm going to ask the question again. If you need to reference this page, go right ahead. Can you explain to me the process that Pearsalls goes through to manufacture Arthrex's FiberTape?
A. In short, a tape component is -- They use the -- a braiding machine. But the carriers are configured in such a way that the braids don't -- the ends of the carriers don't actually cross, and, therefore, it's an open braid which, when it's taken up on the takeup spool it flattens out, makes a tape. That tape is then incorporated -- stitched into a piece of FiberWire suture along its length with a length of -- the length of FiberWires on the ends which have no tape. The middle portion of the construct is FiberWire and FiberTape interstitched, and the ends and the FiberTape ends within the FiberWire, and then there's ends of FiberWire outside of that.
Q. Okay. So does Arthrex's FiberTape include an Arthrex No. 2 FiberWire suture?
A. Yes.
Q. And does it include the Arthrex FiberWire No. 2 suture as depicted in Exhibit 122?

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A. Yes.
Q. Can you just draw for me, please, the cross-section of an Arthrex FiberWire Tape as --
A. Can I -- May I simplify it? Representative of FiberWire and tape without all ...
Q. Sure. You can start about that, and if I'm confused or need more, then I'll let you know. But you can start with that.
MR. TAMBURO: I'm going to object to this line of questioning regarding FiberTape as outside the scope of the notice, which seems to be limited to FiberWire sutures.
MR. FALKE: Well ... I think we defined in our first set of either documentary requests or Interrogatories as FiberWire including FiberWire or any product that includes FiberWire, but your objection is -- you know -- it's your objection.
MR. TAMBURO: I thought I heard a different definition today of FiberWire suture that would not include FiberWire Tape.
MR. FALKE: Right. But I think the notice was probably using the definitions of the other discovery, not necessarily definitions of mine, but --
MR. TAMBURO: Fine. I just wanted to note my objection.

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Q. What is FiberStick, sold under AR-7209?
A. FiberStick is a length of FiberWire that has a -- a long length of it that is tipped or stiffened with the Loc-Tite, and it makes it easier to perform certain actions with.
Q. Other than the difference in the length of stiffening on the end of FiberStick, is there any other difference in any way between FiberStick AR-7209 and the blue FiberWire in AR-7201?
A. Just the overall length is longer.
Q. Okay. So is the structure and configuration in FiberStick AR-7209 the same as the No. 2 FiberWire in Exhibit 122?
MR. TAMBURO: Object to form.
A. Yes.
Q. Does the No. 2 FiberSnare in AR-7209SN have the same structure and configuration as the No. 2 FiberWire in Exhibit 122?
MR. TAMBURO: Same objection.
A. I believe so. I'm not for sure on this one product.
Q. Okay. What's your understanding of what FiberSnare is as sold under AR-7209SN?
A. No, I only understand -- I'm -- I'm familiar on the surface with this product, and I've seen different

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appearances of it, so I can't answer for sure. It doesn't appear -- I've seen it in appearance it looked a little different, so I don't want to answer --
Q. Okay.
A. -- incorrectly.
Q. Okay. Does the No. 2 TigerStick of AR-7209T the same -- have the same structure and configuration as the No. 2 FiberWire in Exhibit 126?
MR. TAMBURO: Object to form.
A. Yes.
Q. Do you understand what I'm saying when I say structure and configuration?
A. Yes, I interpret it as approximately the same makeup.
Q. As that shown?
A. As that shown.
Q. Okay. Does the No. 5 FiberWire AR-7210 have the same structure -- Strike that.
Does the No. 5 FiberWire in AR-7210 have the same structure and configuration as the No. 5 FiberWire shown in Exhibit 122?
MR. TAMBURO: Objection to form.
A. Yes.
Q. And does the No. 5 FiberWire AR-7211 have the same structure and configuration as the FiberWire shown in

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122 -- Exhibit 122?
MR. TAMBURO: Object to form. And it mischaracterizes the exhibit.
A. Yes.
Q. Does the No. 5 FiberWire sold with AR-7219 have the same structure and configuration as the suture shown in Exhibit 122?
MR. TAMBURO: Same objection.
A. Yes.
Q. Okay. Does the No. 5 TigerWire shown or sold with AR-7219 have the same structure and configuration as the No. 2 TigerWire in Exhibit 126?
MR. TAMBURO: Object to form.
A. Yes.
Q. And the No. 2 FiberWire sold under AR-7219, does that have the same structure and configuration as the No. 2 FiberWire shown in Exhibit 122?
MR. TAMBURO: Same objection.
A. Sorry. Did you say FiberWire?
Q. Yeah. Do you want me to repeat it?
A. Please.
Q. Okay. And the No. 2 FiberWire sold under AR-7219, does that have the same structure and configuration as the No. 2 FiberWire shown in Exhibit 122?
MR. TAMBURO: Same objection.

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A. Yes.
Q. And the No. 2 FiberWire sold under AR-7220 and AR-7221, do they have the same structure and configuration as the 2-0 suture shown in Exhibit 121?
MR. TAMBURO: Object to form.
A. Yes.
Q. And the No. 2 -- excuse me. Does the 2-0 FiberStick have the same structure -- Strike that.
Does the 2-0 FiberStick in AR-7222 have the same structure and configuration as the 2-0 FiberWire shown in Exhibit 121?
MR. TAMBURO: Same objection.
A. Yes.
Q. Does the 3-0 FiberWire in AR-7225 and AR-7227-01 and -02 have the same structure and configuration as the 3-0 FiberWire shown in Exhibit 124?
MR. TAMBURO: Same objection.
A. Yes.
Q. Does the 4-0 FiberWire sold under AR-7228, 7230-01, and 7230-02 have the same structure and configuration as the 4-0 FiberWire suture in Exhibit 125?
MR. TAMBURO: Same objection.
A. Yes.
Q. Does the 4-0 FiberLoop in AR-7229-12 and AR-7229-20 have the same structure and configuration as

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

CONTINUATION
DEPOSITION OF: PETER DREYFUSS

DATE: December 7, 2005

TIME: 8:03 a.m. to 1:21 p.m.

LOCATION: The Staybridge Suites
4805 Tamiami Trail North
Naples, FL

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Michael Sturdevant, CLVS

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Q. And if you see in the second paragraph, second sentence, it says, "The Black/White Suture commonly known as TigerWire has a blend of nylon and the ultra high molecular weight polyethylene." Do you see that?
A. Yes.
Q. And if you skip a sentence, it says, "In place of the nylon, a silk suture will be used." Do you see that?
A. Yes, I do.
Q. Is the only difference between Arthrex's TigerWire and Arthrex's FiberWire with silk is the silk suture is used in place of the nylon marker strand in Arthrex's TigerWire product; is that right?
MR. SABER: Object; vague and confusing question.
Q. Do you understand the question?
A. I understand, I believe, from what I read here that that is true.
Q. And the last time we were here, you described the design and construction of the TigerWire product. Do you remember that?
A. Yes, I understand that.
Q. What is the purpose of the nylon marking strand in Arthrex's TigerWire product?
A. Identification. Visual identification.
Q. Is there any other purpose to the nylon marking strand in Arthrex's TigerWire product?

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A. That's the primary purpose. I'm not sure if there's secondary purposes, per se.
Q. Does the introduction of a nylon marking strand in the TigerWire product affect any of the physical characteristics of the TigerWire product?
A. Affect in --
Q. Other than the visual distinction that you can see with the introduction of a nylon marking strand, does the nylon marking strand in TigerWire affect any other characteristic of the braided suture?
A. Yes.
Q. What is -- what?
A. Minute differences in its feel and strength, characteristics.
Q. But you would describe them as minute differences?
A. Not enough to cause it not to become a product.
Q. Can you explain that?
A. It's --
Q. In other words, the introduction of the nylon marking strand doesn't affect any of the marketing qualities or engineering qualities that make FiberWire FiberWire; does that make sense?
MR. SABER: Objection; vague.
A. It -- They are comparable.

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Q. But they show -- But a No. 2 TigerWire, for instance, and a No. 2 FiberWire show very similar knot strength, tensile strength, handleability, and what not, all of the characteristics that define FiberWire?
A. I believe so.
Q. Okay. And is that true also with the introduction of silk rather than a nylon marker?
A. I don't know.
Q. Do you know whether the silk used in the FiberWire with silk suture affects any of the characteristics of the suture?
A. No, I don't.
Q. Based on your understanding of Arthrex's FiberWire with silk product, do you think you would be able to draw a cross-section of the suture?
A. I -- No.
Q. No? But as far as you know, the only difference between the TigerWire and a FiberWire with silk is instead of the nylon, it's a piece of silk?
A. That would be a good generalization.
Q. Okay. And Don Grafton would know this information?
A. I believe so, yes.
(DePuy Mitek Exhibit No. 142, Design History File for FiberWire 3-0 and 4-0, ARM 6580 through 6950, was

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marked for identification.)
Q. I'm going to hand you a document labeled DePuy Mitek Exhibit 142. It's a document with Bates numbers ARM 6580 through 6950.
Have you seen Exhibit 142 before?
A. I believe so.
Q. And what is DePuy Mitek Exhibit 142?
A. The Design History File for FiberWire new sizes -- new sizes of FiberWire.
Q. And what new sizes for FiberWire?
A. 3-0 and 4-0.
Q. Do you have any reason to believe the information in Exhibit 142 is inaccurate?
MR. SABER: Objection; overbroad.
A. No, I don't.
MR. FALKE: I'm just trying to authenticate the document.
MR. SABER: No, I have no problem with you authenticating the document, but I -- you know -- this is, again, a document of hundreds of pages. And to ask him to -- a generalized question like that I think is kind of unfair.
BY MR. FALKE:
Q. Do the instructions for use that are included with all of Arthrex's FiberWire product indicate that the

BROOKSTEIN DECLARATION EXHIBIT 9

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

December 2, 1992
(Date of Deposit)

Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

(Signature)

December 2, 1992
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

Please reconsider the above-identified application in view of the following remarks. These remarks are subdivided into a discussion of the claimed invention, and an analysis of the rejection, to facilitate an understanding of the significant differences between the cited art and the claimed invention.

Discussion of the Invention

A proper understanding of the invention is critical for appreciating the dissimilarities between the invention and the teachings of the cited references.

In a broad sense, the invention is a braided suture which contains dissimilar filaments of first and second fiber-forming materials. However, the proper characterization of the claimed suture goes far beyond this simple description.

The braided suture is made up of multifilament yarns. A multifilament yarn is a bundle of individual filaments which are integrated to form a single unit, that is, an individual multifilament yarn. The braided suture has a first and second set of these multifilament yarns in a braided construction. Each of the filaments of the first set of yarns is composed of a first fiber-forming material. Similarly, each of the filaments of the second set of yarns is composed of a second fiber-forming material.

The importance of the construction of the first and second set of yarns cannot be diminished. The braided construction is not accurately characterized by simply referring to a suture with filaments of dissimilar fiber-forming materials in a braided construction. Rather, filaments of a first fiber-forming material must be bundled to prepare a first set of multifilament yarns, and filaments of the second fiber-forming material must also be bundled to prepared the second set of multifilament yarns.

Once an understanding of the composition and construction of each set of first and second yarns is achieved, the importance of a further characterization of the braid construction can now be understood and appreciated. One yarn from the first set of yarns is in direct intertwining contact with a yarn from the second set of yarns. This limitation does not simply mean that the dissimilar filaments are fabricated into a braided construction, that is, dissimilar filaments are in "intertwining contact". Rather it is a multifilament yarn which is in direct intertwining contact with another multifilament yarn. Again, it is important to emphasize here that the multifilament yarns are integrated bundles of individual filaments, and it is this integrated bundle of filaments of a first fiber-forming material which is in direct intertwining

contact with another integrated bundle of individual filaments of a second fiber-forming material.

One way to accurately characterize the braided suture of this invention is to refer to it as a structured mechanical blend of dissimilar fiber-forming materials. The fiber-forming materials are first arranged into integrated bundles to form multifilament yarns and then these multifilaments yarns are further arranged so that at least one yarn from the first set of yarns directly intertwines with a multifilament yarn from the second set of yarns. This can be contrasted with a random, braided construction where filaments of dissimilar fiber-forming materials are randomly braided with one another to form a braided suture.

The heterogeneous braids of this invention exhibit truly outstanding and surprising properties. The integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual multifilament yarns (see the specification at page 4, lines 30-33). In the preferred embodiment, each yarn from the first set of multifilament yarns is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar multifilament yarns (see the specification at page 6, lines 28-31, and claim 15). In this way, yarn compatibility can be further enhanced and the overall physical and biological properties of the heterogeneous braid can be further improved as well.

What is truly surprising with respect to the claimed heterogeneous braid construction is that certain bulk properties of the claimed braid are better than what one skilled in the art would expect. A skilled artisan would expect the properties of the braid to simply follow the "Rule of Mixtures", where the bulk property

measured would be estimated to be a weighted average of its component properties. Upon studying the Examples in the specification, it will be noted that the bending rigidity of the heterogeneous braids in Examples 1 and 2 do not follow the Rule of Mixtures, but surprisingly show an enhanced bending rigidity relative to the weighted average of their filament components. This behavior is not achieved when dissimilar individual filaments are randomly braided to form the braided suture.

In setting forth the claimed invention, the heterogeneous braid does not encompass braided sutures with randomly braided individual filaments, as described in detail above. Further, the claimed heterogeneous braid could not be construed to cover known braids which have a core of longitudinally extending yarns composed of filaments of a first fiber-forming material, and a sheath of braided yarns composed of a second set of filaments of a dissimilar fiber-forming material. This braid construction does not fall within the scope of the claimed braid because these sheath yarns are not in direct intertwining contact with any of the core yarns. In other words, none of the sheath yarns are braided about a core yarn, but simply shroud the core yarns to form the sheath construction.

Analysis of the Rejection

1. Claims 21 and 23 were rejected under 35 USC §102(b) as being clearly anticipated by Doddi et al. ("Doddi"). Doddi does not anticipate the claimed suture, and therefore this rejection should be withdrawn.

The Examiner has correctly pointed out that Doddi does indeed disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56).

However, as discussed in detail above, more is required to meet the limitations of the claimed suture than just a disclosure concerning filaments of two different polymers in a braided configuration. Doddi teaches nothing more than braiding individual filaments, and fails to provide any guidance as to how that braiding should be carried out. Therefore, one skilled in the art would be lead to believe that what Doddi had in mind was to simply braid individual filaments in a randomized fashion to fabricate a multifilament suture. It is important enough, however, to reemphasize again that the claimed braid requires the bundling of individual filaments into an integrated unit to form a multifilament yarn. It is this multifilament yarn which directly intertwines with another multifilament yarn to form Applicants' braid construction.

Since Doddi only teaches randomly braiding filaments of dissimilar fiber-forming materials, it does not anticipate the claimed braided suture. Doddi simply fails to enable one skilled in the art to construct a braided suture in the manner set forth by Applicants, and it is axiomatic that a reference which lacks enablement is deficient as a reference to anticipate a claimed invention. Accordingly, it is respectfully requested that the rejection of claims 21 and 23 under 35 USC §102(b) as being clearly anticipated by Doddi be withdrawn.

2. Claims 22 and 24 were rejected under 35 USC §103 as being unpatentable over Kaplan et al. ("Kaplan") taken with Doddi. The Examiner asserts it would have been obvious to substitute PET and PTFE fibers of Doddi for the filaments of Kaplan to arrive at Applicants' claimed suture. Applicants respectfully traverse this rejection for the reasons given below.

The Examiner correctly points out that Kaplan discloses a ligament prosthesis made from a core component and a braided sheath component as illustrated in Figures 3 and 4, and discussed at column 8, line 65, through column 9, line 34. However, Kaplan suffers from the same deficiencies as does Doddi, and therefore fails to teach or suggest the claimed braided suture.

Firstly, the Examiner has made specific reference to the Kaplan specification regarding the makeup of the core components and the sheath yarn component. The only component which has a braided construction is the sheath yarn component. It is clear from Figure 3 of Kaplan that none of the sheath yarn components are in direct intertwining contact with the core component. In other words, the sheath yarn component is a true "sheath" which shrouds the core but is not in any way integrally braided with the core. Therefore, since the core is not in a braided construction, its composition is irrelevant with respect to the claimed braided suture.

When the focus is shifted to the more relevant aspect of the Kaplan disclosure, specifically the sheath yarn component, the Examiner has correctly pointed out that the sheath yarn component may be "fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being non-absorbable". (Column 9, lines 25-28). However, Kaplan neither teaches nor suggests how his sheath yarn component is to be fabricated from these dissimilar individual filaments, nor is there any guidance to one skilled in the art as to how such dissimilar individual filaments are to be braided. Accordingly, just as was the case with the deficient Doddi reference, one skilled in the art could only be lead to randomly braid the dissimilar individual filaments into a braid construction.

The teaching of Kaplan once again lacks the essence of the claimed invention, which is: bundled filaments of a first fiber-forming material form a first set of a multifilament yarns, and at least one of these multifilament yarns is intertwined with a multifilament yarn composed of bundled filaments of a second fiber-forming material. To put it bluntly, Kaplan teaches randomized braiding, and the claimed suture sets forth a structured braid. This difference is not trivial, as pointed out with reference to the discussion of Applicant's specification, and particularly Examples 1 and 2.

It should also be pointed out here that even if Doddi and Kaplan were combined, their combined teachings would still fail to meet the limitations of the claimed braided suture. This is so because neither reference, taken singularly or in combination, discloses a structured braid set forth in the claims, but merely sets forth randomized braiding of individual filaments.

For all of the reasons given above, especially taken in light of the detailed discussion of the claimed braided suture and its surprising advantages, the rejection of claims 22 and 24 under 35 USC §103 as being unpatentable over Kaplan taken with Doddi is improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

3. Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants' response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed

invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

4. The prior art made of record and not relied upon by the Examiner is duly noted, and does not affect the patentability of Applicants' claimed invention.

5. Since all formal requirements appear to have been met, and the claimed invention is patentable over the art of record or any other art of which Applicants are aware, Applicants respectfully solicit a Notice of Allowance at the Examiner's earliest convenience.

Respectfully submitted,

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BROOKSTEIN DECLARATION EXHIBIT 10

Marks' Standard Handbook for Mechanical Engineers

Revised by a staff of specialists

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Table 1. Fiber Properties*

Kind	Source	Length of fiber, in.	Width or diam of cells, microns	Specific gravity	Moisture regain,‡ percent	Chemical description	Principal uses
Cotton	Plant seed hair	5/8–2	8–27	1.52	8.5	Cellulose	Industrial, household, apparel
Jute†	Plant bast	50–80	15–20	1.48	13.7	Lignocellulose	Bagging, twine, carpet backing
Wool	Animal	2–16	10–50	1.32	17	Protein	Apparel, household, industrial
Viscose	Manufactured	Any	8–43	1.52	11	Regenerated cellulose	Apparel, industrial, household
Cellulose acetate	Manufactured	Any	12–46	1.33	6	Cellulose ester	Apparel, industrial, household
Nylon	Manufactured	Any	8	1.14	4.2	Polyamide	Apparel, industrial, household
Casein	Manufactured	Any	11–28	1.3	4.1	Protein	Apparel
Flax†	Plant bast	12–36	15–17	1.5	12	Cellulose	Household, apparel, industrial
Hemp†	Plant bast	.....	18–23	1.48	12	Cellulose	Twine, halyards, rigging
Sisal†	Plant leaf	30–48	10–30	....	....	Lignocellulose	Twine, cordage
Manila†	Plant leaf	60–140	10–30	....	....	Lignocellulose	Rope, twine, cordage
Ramie†	Plant bast	3–10	24–70	1.52	....	Cellulose	Household, apparel, seines
Silk	Silkworm	Any	5–23	1.35	11	Protein	Apparel, household, industrial
Glass	Manufactured	Any	3	2.5	0	Fused metal oxides	Industrial, household
Dacron	Manufactured	Any	8	1.38	0.4	Polyester	Apparel, industrial, household

1 in = 0.0254 m; 1μ = 10^{-6} m. The more up-to-date term for the micron (μ) is the micrometer (μm).

*Adapted from Smith, Textile Fibers, *Proc. ASTM*, 1944; Appel, A Survey of the Synthetic Fibers, *Am. Dyestuff Reporter*, 34, 1945. pp. 21–26; and other sources.

†These fibers are commercially used as bundles of cells. They vary greatly in width. Width figures given are for the individual cells.

‡In air at 70°F and 65 percent relative humidity.

Table 2. Tensile Properties of Single Fibers*

Fiber	Breaking tenacity, gpd	Extension at break, percent	Elastic recovery at corresponding strain, percent	Elastic modulus,† gpd
Glass	6.0–7.3	3.0–4.0	100 at 2.9	200–300
Fortisan (rayon)	6.0–7.0	6	100 at 1.2 60 at 2.4	150–200
Flax	2.6–7.7	2.7–3.3	65 at 2	
Nylon 6, 6	4.6–9.2	16–32	100 at 8	25–50
Nylon 6	4.5–8.6	16–40	100 at 8	25–50
Silk	2.4–5.1	10–25	92 at 2	75–125
Saran	1.1–2.3	15–25	95 at 10	
Cotton	3.0–4.9	3–7	74 at 2	50–100
Steel (90,000 psi T.S.)	0.9	28	.....	300
Steel (music wire)	3.5	8	.....	300
Viscose rayon	1.5–5.0	15–30	82 at 2	50–150
Wool	1.0–1.7	25–35	99 at 2	25–40
Acetate rayon	1.3–1.5	23–34	100 at 1	25–40
Polyester	4.4–7.8	10–25	100 at 2	50–80
Polypropylene	4.0–7.0	15–25	95 at 7	15–50
Polytetrafluoroethylene	1.7	13	.....	

*From Kaswell, "Wellington Sears Handbook of Industrial Textiles," Wellington Sears Co., Inc.

†From Kaswell, "Textile Fibers, Yarns, and Fabrics." Reinhold.